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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,020	09/15/2000	Jeffery W. Bacher	16026-9267	1823

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EXAMINER

CHUNDURU, SURYAPRABHA

ART UNIT PAPER NUMBER

1637

DATE MAILED: 12/16/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

file

**Office Action Summary**

Application No.

09/663,020

Applicant(s)

BACHER ET AL.

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 30,35-47,52 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9-19,21,24-28,50 and 53 is/are rejected.
- 7) ☒ Claim(s) 6,20,22,23,31-34,48,51 and 54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. Applicants' response to the office action and amendment (Paper No. 11) filed on April 11, 2002 has been entered.
2. The Supplemental IDS (Paper No. 12) filed on April 12, 2002 has been entered and considered.

**New issues**

3. Claims 30, 49, 52, and 55 depend on non-elected SEQ ID Nos. or species and hence are withdrawn from further consideration.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 22 recites the limitation "the set of at least two microsatellite loci" in a set. There is insufficient antecedent basis for this limitation in the claim because the claim 16 upon which the instant claim 22 depends, recites a set of at least three microsatellite loci which excludes a set of at least two microsatellite loci. Therefore, claim 22 lacks antecedent basis.

***Double Patenting***

5. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-3, 7, 9-15, 50, 53 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 41-45, 47-48, 51-56 copending Application No. 09/841, 366. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

a. Claims 1-5, 9-12, 14-19, 21, 24-26, 28, 50, 53 are rejected under 35 U.S.C. 102(b) as being anticipated by Frazier et al. (Oncology Reports, Vol. 6, pp. 497-505, 1999).

Frazier et al. teach a method for analyzing micro-satellite loci (five loci), the method comprising (a) providing primers for co-amplifying a set of at least three microsatellite loci of genomic DNA (see page 499, column 2, paragraphs 1-2); (b) co-amplifying set of at least three microsatellite loci in a multiplex amplification reaction comprising said primers and producing

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amplified DNA fragments (see page 499, column 2, paragraph 2); and (c) determining the size of the amplified DNA fragments (see page 499, column 2, paragraph 2). Frazier et al. also teach that the microsatellite loci comprise mono and tetra nucleotide repeat (BAT26, FGA)(see page 497, column 1, abstract, page 499, column 2, table II); at least one oligonucleotide primer for each locus was fluorescently labeled (see page 500, column 2, paragraph 1); sample comprises normal DNA from a patient and DNA originating from a tumor and detection of microsatellite instability by comparing the size of the amplified DNA fragments (see page 501, column 2, paragraph 1, page 502, Figure. 3); method comprises correlation between MSI with prognosis and familial tumor predisposition (page 504, column 1, paragraph 4, page 503, column 2, paragraph 3); cancerous tumors were from a colorectal cancer (see page 497, column 1, abstract, page 498, column 2, paragraphs 1-2); the tumor sample comprises tumor tissue, blood cells (see page 498, column 2, paragraph 2, page 499, column 2, paragraph 1). Thus the disclosure of Frazier et al. meets the limitations in the instant claims.

b. Claims 1-5, 10-19, 24-28, 50, 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Ruschoff et al. (USPN. 6,150,100).

Ruschoff et al. teach a method for genomic instability (micro-satellite instability) at selected micro-satellite loci wherein Ruschoff et al. disclose that the method comprises (i) isolating DNA from human biological material, providing primers for each set of micro-satellite loci comprising mononucleotide repeat locus, dinucleotide repeat loci, tetranucleotide repeat loci, pentanucleotide loci (see column 6, lines 33-43) amplifying the set of micro-satellite loci of sample DNA and determining the size of amplified DNA fragments (see column 3, lines 7-18). Ruschoff et al. also disclose that the method comprises (i) multiplex analysis (see column 5, lines

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14-19, column 6, lines 49-50); (ii) genomic DNA from normal tissue (non-cancerous) and genomic DNA from tumor tissue (see column 30, lines 43-59); the biological material includes DNA isolated from tumor tissue, body fluids such as blood, serum, plasma, urine or faeces (see column 4, lines 17-25); (iii) the method is applicable to prognostic diagnosis of tumors and analysis of these loci was suitable (used) for making prognostic tumor diagnosis, tumor predisposition as well as detection of tumors of endometrium, the gastrointestinal tract and in particular colorectal tumors (see column 3, lines 42-45, column 10, lines 18-33). Thus the disclosure of Ruschhoff et al. meets the limitations in the instant claims.

### ***Response to Arguments***

7. Applicants' response to the office action (Paper No.11) is fully considered and deemed persuasive.
8. The rejection made under 35 U.S.C. 112 second paragraph in the previous office action is withdrawn herein in view of the applicants' arguments and amendment (Paper No.11).
9. With respect to the rejection made in the previous office action under 35 U.S.C. 103(a), Applicants' arguments (Paper No. 11) with respect to claims 1-2, 4-16, 18-34 are considered but found persuasive in part. Applicants' arguments regarding no suggestion or motivation to combine the references is found persuasive with respect to the claims 6, 7-8, 20, 22-23, 29, 31-34. However, Applicants arguments that the prior art Ruschhoff et al. did not teach the limitation "analyzing or detecting microsatellite instability comprising at least three microsatellite loci comprising at least one mono and at least two tetranucleotide loci" was found not persuasive because Ruschhoff et al. did teach duplex or multiplex analysis (see column 5, lines 14-19) and co-amplification of 25 loci which include the limitation of at least one mononucleotide repeat

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locus and at least two tetranucleotide repeat loci as claimed in the instant independent claims 1, 5 and 15. The rejection is re-written herein as above.

*Allowable Subject Matter*

10. Claims 6, 20, 22-23, 31-34, 48, 51, 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and specifically limiting the claims to MONO-15. Claim 29 is objected for being dependent on non-elected species MONO-11, but would be allowable if the claim is rewritten in independent form specifically limiting the claim to MONO-15.


*Conclusion*


No claim is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
December 12, 2002

  
JEFFREY FREDMAN  
PRIMARY EXAMINER